K131392

Secure Medical Networking

MAY 2 9 2013

510(k) Summary
of Safety and Effectiveness

This 510(k) summary of Safety and Effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

March 22, 2013

Submitter's Information: 21 CFR 807.92(a)(1)

Eric Le Bihan
President
ETIAM S.A.S .U.
2 rue Pierre-Joseph Colin
35000, Rennes - France
Tel: +33 299 143388
Fax: +33 299 143380
Email: eric.lebihan@etiam.com

Name, title and phone number of contact: 21 CFR 807.92(a)(1)

Géraldine Tessens
Quality Manager
Tel: +33 299 143386
Fax: +33 299 143380
Email: geraldine.tessens@etiam.com

Name of the device: 21 CFR 807.92(a)(2)

- Trade name: ETIAM PACS Components™
- Common name: Picture, Archive and Communications System
- Classification name: system, image processing, radiological (21 CFR 892.2050, Product Code LLZ)

Predicate Devices: 21 CFR 807.92(a)(3)

- 510(k) number K052358
  Regulation number 892.2050
  Device name ETIAM STAR PACS COMPONENTS
  Applicant ETIAM, S.A.S.U.
  Classification product code LLZ
  Device classification name SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
  Class II
  Panel Radiology Device

- 510(k) number K062488
  Regulation number 892.2050
  Device name iQ-System PACS
  Applicant IMAGE INFORMATION SYSTEMS, LTD.
  Classification product code LLZ
  Device classification name SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
  Class II
  Panel Radiology Device

- 510(k) number K083618
  Regulation number 892.2050
  Device name PACS SCAN
  Applicant PACSGEAR, INC
  Classification product code LLZ
  Device classification name SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
  Class II
  Panel Radiology Device

Device Description: 21 CFR 807.92(a)(4)

ETIAM PACS Components™ are software applications that make possible the capturing, storage, distribution, and networking of medical images at distributed locations. In cases where DICOM images are not directly available to ETIAM PACS Components™, the system can acquire medical images using a DICOM gateway, which generates DICOM-type files. For example, film digitizers obtain images from old film and convert them to meet DICOM standards and stored in an archive. Stored files are transmitted using a network and can be viewed or manipulated from an imaging workstation.

Intended Use: 21 CFR 807.92(a)(5)

ETIAM PACS Components™ is intended to be used by healthcare personnel to import, review, edit and send medical images.

ETIAM PACS Components™ is not labeled for diagnostic use.

ETIAM PACS Components™ is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that meets other technical specifications reviewed and accepted by FDA.

Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, medical technicians, and assistants.

Technological Characteristics: 21 CFR 807.92(a)(6)

ETIAM PACS Components™ is a software product that handles digital medical images.

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

The design, fundamental technology, functionalities, intended use and performances of the ETIAM PACS Components™ are similar and therefore substantially equivalent to its three predicates like it is demonstrated in the table below.

Spécification	ETIAM PACS Components™	ETIAM STAR PACS Components™	iQ-System PACS	PACS SCAN
Comparison of multiple studies	YES	YES	YES	YES
Measurements	YES	YES	YES	YES
Annotation of images	YES	YES	YES	YES
DICOM Query/Retrieve, DICOM Print Client	YES	YES	YES	YES
JPEG lossy/lossless compression	YES	YES	YES	YES
TWAIN interface	YES	YES	YES	YES
Image file import	YES	YES	YES	YES
Patient CD/DVD import	YES	YES	YES	YES
Create Patient CD, DVD	YES	YES	YES	YES
Export to memory stick	YES	YES	YES	YES
Windows print	YES	YES	YES	YES
Image export to image file or AVI video file	YES	YES	YES	-
Integration of direct interface to an automatic publisher for patient CD/DVD creation	YES	YES	YES	YES
Review report (SR formats)	YES	YES	YES	YES
Manipulating images	YES	YES	YES	YES
Interface to RIS worklist or DICOM Archive	YES	YES	YES	YES
Video capture interface	YES	NO	YES	YES
Digitize film	YES	YES	NO	YES
Edit patient demographics	YES	YES	YES	YES

Non-clinical performance

Every specification of the ETIAM PACS Components™ is validated by a test bench carried out during before release. The bench testing includes:

- The package (documentation included)
- The installation of the software
- The configuration of the software
- The management of the patient-study information
- The acquisition and integration of new data
- The manipulation of the data
- The DICOM conversion
- The DICOM connectivity
- The export and distribution of data

Cinical performance

Our device only utilizes standard lossy (irreversible) compression techniques defined and supported by DICOM Standard. Only the administrator can activate the compression function of the device.

So clinical studies were deemed unnecessary to evaluate the safety or effectiveness of ETIAM PACS Components™.

Conclusion: 21 CFR 807.92(b)(1)

The 510(k) Pre-Market Notification for ETIAM PACS Components™ contains adequate information and data to enable FDA-CDRH to determine substantial equivalence to the predicate device.

ETIAM PACS Components™ has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern" for potential hazard has been classified as "Moderate".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2013

Etiam S.A.S.U.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K131392
Trade/Device Name: ETIAM PACS Components™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 10, 2013
Received: May 14, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131392

Device Name: **ETIAM PACS Components™**

Indications for Use:

ETIAM PACS Components™ is intended to be used by healthcare personnel to import, review, edit and send medical images.

ETIAM PACS Components™ is not labeled for diagnostic use.

ETIAM PACS Components™ is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that meets other technical specifications reviewed and accepted by FDA.

Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, medical technicians, and assistants.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K131392